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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,152	02/26/1999	KENICHI HIGASHIYAMA	001560-344	6530

7590 07/16/2002

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/16/2002 20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/254,152	Applicant(s) HIGASHIYAMA ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,14,19,20 and 23-46* is/are pending in the application.

4a) Of the above claim(s) *19,20,23-28,31 and 37-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,14,29,30 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9&19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 19, 20, 23-28, 31 and 37-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

2. Applicant's election with traverse of invention group I, claim 13, 14 and 29-36 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that search of all the invention is not an undue burden to the examiner. This is not found persuasive because these inventions are distinct for the reasons given in the prior office action and the search required for Groups II or III is not required for Group I. Further, the search is not limited to patent literature, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on the elected species.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 13, 14, 29, 30 and 32-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,117,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matters in '905 is essentially the same as claimed herein, except claims of '905 have a narrower scope with respect to the amount of 24, 25-methylenecholest-5-en-3b-ol, and have broad scope with respect to the amount of arachidonic acid (30-50% herein vs. more than 20% in '905). Though claim 5 in '905 does not expressly claim infant formula, however, the claimed food including infant food. See the abstract of '905.

Claim Rejection 35 USC – 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 13, 14, 29, 30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmen et al (of record) in view of both of Shimizu et al (of record) and Barclay (of record).

Shinmen et al. teach an unsaturated fatty acid-containing oil obtained from culturing of microorganism *Mortierella* contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen also teach the nutritive effect of arachidonic acid. See, particularly, the introduction on page 11.

Shinmen et al. do not teach how much of 24,25-methylenecholest-5-en-3β-ol is present in the oil. Shinmen do not teach the employment of such oil in food products including baby food and animal food.

However, Shimizu et al. teach that unsaturated fatty acid-containing oil obtained from culturing microorganism Mortierella has 24,25-methylenecholest-5-en-3β-ol which has not been found in nature, i.e., not found in any natural food such as breast milk and its biological activity and toxicity have not been fully evaluated. See, particularly, the abstract on page 481. Barclay teaches the employment of arachidonic acid containing oil obtained from culturing microorganism Mortierella for food product including baby food and animal food. See, particularly, column 7, line 48-60.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the unsaturated fatty acid-containing oil of Shinmen et al. by *removing* the biologically unknown compound, i.e., 24,25-

methylenecholest-5-en-3β-ol and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement.

A person of ordinary skill in the art would have been motivated to remove 24,25-methylenecholest-5-en-3β-ol from the unsaturated fatty acid-containing oil and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement *because the biological activity of 24,25-methylenecholest-5-en-3β-ol is not known and it would not be safe to use such oil in baby food.* Methods of removing the compound such as chromatography separation or modification of fermentation conditions are considered within the skill of artisan. Furthermore, employment of unsaturated fatty acid-containing oil in food products are known.

The specification appears to disclose an oil composition obtained through an improved microbial process which containing less unwanted ingredient than those obtained through a known microbial process. A product by process claim would be favorably considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

Shengjun Wang

July 5, 2002